REMARKS/ARGUMENTS

Objection to the specification

The Examiner has objected to the incorporation of allegedly essential material into the specification by reference. According to the Examiner, the polypeptide sequence of BRC 456 is essential, and cannot be defined by Genbank Accession number.

Applicants do not agree with the Examiner's position, because one of skill would recognize and know how to obtain a BRC No. 456 polypeptide given the name of the gene (TOPK), and the exemplary sequences in Genbank Accession Numbers AF237709 and NM_018492. However, in an effort to expedite prosecution, Applicants have added to the Substitute Sequence Listing both the polypeptide and polynucleotide sequences of the respective Genbank entries as of the priority PCT application filing date. The SEQ ID NOS: are also added to the specification by the present amendment. SEQ ID NO:49 is the polypeptide sequence of Genbank Accession Number AF237709, and SEQ ID NO:48 is the polynucleotide sequence (*see* **Ex. A**). SEQ ID NO:51 is the polypeptide sequence of Genbank Accession Number NM_018492, and SEQ ID NO:50 is the polynucleotide sequence (*see* **Ex. B**). The Genbank Accession Numbers were intended as examples of a known protein, and sequences of SEQ ID NOS:49 and 51 are considered exemplary polypeptide sequences.

Further, a thorough review of the application revealed additional sequences entered into the Substitute Sequence Listing as SEQ ID NOS:32-47. These sequence identifiers have also been inserted into the proper locations in the Specification by the present amendment.

Applicants also submit herewith a Declaration under 37 CFR 1.132 from the Applicants' representative stating that the amendatory material consists of the same material incorporated by reference. Copies of the Genbank entries are enclosed as **Ex. A** and **B**.

Status of the claims

Claims 20, 23, 25, and 28 are pending. Claims 98 and 99 are cancelled and the pending claims are amended. Support for the amendments is found, *e.g.*, on page 10, paragraph [0027], and pages 20-22, paragraphs [0078]-[0091].

Rejection under 35 USC § 112, first paragraph -- Enablement

Claims 20, 23, 25, and 28 are rejected as allegedly lacking enablement. According to the Examiner, the specification enables a method of screening comprising contacting test compounds with TOPK (encoded by BRC No. 456), selecting compounds that suppress kinase activity of TOPK..., selecting compounds that suppress cell growth..., and selecting compounds that bind to TOPK, wherein the selected compounds are candidate compounds to prevent and treat breast cancer. The Examiner alleges that the specification does not enable (i) screening for a compound that prevents and treats breast cancer or (ii) screening using any polypeptide encoded by any polynucleotide of a gene of BRC No. 456.

In an effort to expedite prosecution, Applicants have amended the description of the methods so that they are directed to suppressing the growth of a breast cancer (or IDC) cell. As amended, the claims also recite a step of selecting a compound that suppresses the cell growth of a breast cancer (or IDC) cell.

Also in an effort to expedite prosecution, Applicants have amended the description of the polypeptide used in the claimed methods, as suggested by the Examiner. As amended, the claims recite contacting a test compound with T-LAK cell-originated protein kinase (TOPK).

In view of the foregoing comments, Applicants respectfully request withdrawal of the rejection under the first paragraph of 35 USC § 112 for enablement.

Rejection under 35 USC § 102

The Examiner has rejected claims 20, 23, 25, and 28 as allegedly anticipated by Mack (US20040005563). The Examiner asserts that Mack teaches a method of screening using the PDZ binding kinase (BRC No. 456, TOPK) and selecting a compound that binds the kinase, reduces kinase activity, or suppresses cell growth (*see* Office Action, page 14). To the extent the rejection applies to the amended claims, Applicants respectfully traverse.

Mack focuses entirely on ovarian cancer and discloses 20 tables full of genes with different expression levels associated with ovarian cancer. Mack does not mention breast cancer,

or associate PDZ binding kinase with breast cancer. Moreover, Mack fails to teach that PDZ binding kinase (BRC No. 456, TOPK) is involved in cell growth. The reference simply lists 1000s of genes, without disclosing that a compound that binds to any of the encoded polypeptides will inhibit cell growth. Thus, Mack does not disclose a method of screening for compounds that suppress PDZ binding kinase (BRC No. 456, TOPK) *and* cell growth.

As amended, the claims recite a step of contacting a selected test compound with a breast cancer (or IDC) cell. Mack does not mention breast cancer, and therefore does not anticipate the present claims. In view of the foregoing comments, Applicants respectfully request withdrawal of the rejection under 35 USC § 102.

CONCLUSION

Applicants request entry of this amendment in adherence with 37 C.F.R. §§1.821 to 1.825. This amendment is accompanied by a computer readable form containing the above named sequences, SEQ ID NOS:1-52, and a paper copy of the sequence information which has been printed from the computer readable form.

The information contained in the computer readable form was prepared through the use of the software program "FastSEQ" and is identical to that of the paper copy. This amendment contains no new matter.

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

Carol Johns

Carol P. Johns
Reg. No. 50,463

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Attachments
CPJ:cpj/dmw
61680924 v1

1: AF237709. Reports Homo sapiens sper...[gi:8037848] Links

Features Sequence

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VERSION     AF237709.1  GI:8037848
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            Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini;
            Catarrhini; Hominidae; Homo.
REFERENCE   1  (bases 1 to 1840)
  AUTHORS   Zhao,S., Dai,J., Zhao,W., Xia,F., Zhou,Z., Wang,W., Gu,S., Ying,K.,
            Xie,Y. and Mao,Y.
  TITLE     PDZ-binding kinase participates in spermatogenesis
  JOURNAL   Int. J. Biochem. Cell Biol. 33 (6), 631-636 (2001)
   PUBMED   11378444
REFERENCE   2  (bases 1 to 1840)
  AUTHORS   Mao,Y., Xie,Y., Zhao,S., Zhao,W., Wang,W., Zhou,Z., Huang,Y.,
            Wang,S., Tang,R., Chen,X. and Wu,C.
  TITLE     Cloning of a new human kinase gene
  JOURNAL   Unpublished
REFERENCE   3  (bases 1 to 1840)
  AUTHORS   Mao,Y., Xie,Y., Zhao,S., Zhao,W., Wang,W., Zhou,Z., Huang,Y.,
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  TITLE     Direct Submission
  JOURNAL   Submitted (21-FEB-2000) Institute of Genetics, School of Life
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REFERENCE   1  (bases 1 to 1899)
  AUTHORS   Simons-Evelyn,M., Bailey-Dell,K., Toretsky,J.A., Ross,D.D.,
            Fenton,R., Kalvakolanu,D. and Rapoport,A.P.
  TITLE     PBK/TOPK is a novel mitotic kinase which is upregulated in
            Burkitt's lymphoma and other highly proliferative malignant cells
  JOURNAL   Blood Cells Mol. Dis. 27 (5), 825-829 (2001)
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            development.
REFERENCE   2  (bases 1 to 1899)
  AUTHORS   Zhao,S., Dai,J., Zhao,W., Xia,F., Zhou,Z., Wang,W., Gu,S., Ying,K.,
            Xie,Y. and Mao,Y.
  TITLE     PDZ-binding kinase participates in spermatogenesis
  JOURNAL   Int. J. Biochem. Cell Biol. 33 (6), 631-636 (2001)
   PUBMED   11378444
REFERENCE   3  (bases 1 to 1899)
  AUTHORS   Abe,Y., Matsumoto,S., Kito,K. and Ueda,N.
  TITLE     Cloning and expression of a novel MAPKK-like protein kinase,
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  JOURNAL   J. Biol. Chem. 275 (28), 21525-21531 (2000)
   PUBMED   10781613
REFERENCE   4  (bases 1 to 1899)
  AUTHORS   Gaudet,S., Branton,D. and Lue,R.A.
  TITLE     Characterization of PDZ-binding kinase, a mitotic kinase
  JOURNAL   Proc. Natl. Acad. Sci. U.S.A. 97 (10), 5167-5172 (2000)
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Last update: Wed, 05 Nov 2008 Rev. 145015